Groups 1-20, claims 1 and 7 drawn to a method for diagnosis of the presence of prostate cancer comprising determining the level of a cancer specific gene or CSG of SEQ ID Nos:1-20;

Groups 21-40, claims 1 and 7, drawn to a method for diagnosing the presence of prostate cancer comprising determining the level of a cancer specific gene product encoded by SEQ ID Nos: 1-20;

Groups 41-60, claims 2, 4 and 7, drawn to a method for diagnosing the presence of metastasis of prostate cancer or monitoring onset of metastasis comprising determining the level of a cancer specific gene or CSG of SEQ ID Nos: 1-20;

Groups 61-80, claims 2, 4 and 7, drawn to a method for diagnosing the presence of metastasis of prostate cancer or monitoring onset of metastasis comprising determining the level of a cancer specific gene product encoded by SEQ ID Nos: 1-20;

Groups 81-100, claims 3, 5 and 7, drawn to a method for staging prostate cancer or monitoring changes in stages of prostate cancer comprising determining the level of a cancer specific gene or CSG of SEQ ID Nos: 1-20;

Groups 101-120, claims 3, 5 and 7, drawn to a method for staging prostate cancer or monitoring changes in stages of

prostate cancer comprising determining the level of a cancer specific gene product encoded by SEQ ID Nos: 1-20;

Groups 121-140, claims 6 and 7, drawn to a method for identifying therapeutic agents comprising screening for molecules that bind to a cancer specific gene or CSG of SEQ ID Nos:1-20;

Groups 141-160, claims 6 and 7, drawn to a method for identifying therapeutic agents comprising screening for molecules that bind to a cancer specific gene product encoded by SEQ ID Nos:1-20;

Groups 161-180, claim 8, drawn to an antibody which specifically binds to a cancer specific gene product encoded by SEQ ID Nos:1-20;

Groups 181-200, claims 9 and 10, drawn to a method of imaging prostate cancer comprising administering an antibody that specifically binds to a cancer specific gene product encoded by SEQ ID Nos:1-20;

Groups 201-220, claim 11, drawn to a method of treating prostate cancer comprising administering an antibody which specifically binds to a cancer specific gene product encoded by SEQ ID Nos:1-20;; and

Groups 221-240, claim 12, drawn to a method of treating prostate cancer comprising administering an antibody conjugated to a cytotoxic agent.

With respect to the CSGs of SEQ ID Nos:1-20 and the gene products encoded thereby, the Examiner suggests that each constitutes a single invention, and not a species.

Further, the Examiner suggests with respect to Groups 1-120 that election between the patentably distinct species of cells and tissues or bodily fluids is required.

With respect to Groups 41-80, the Examiner suggests that election between the patentably distinct species of metastasis or onset of metastasis is required;

With respect to Groups 81-100, the Examiner suggests that election between the patentably distinct species of staging prostate cancer and monitoring changes in stage of prostate cancer is required.

With respect to Groups 121-160, the Examiner suggests that election between the patentably distinct species of imaging and treating prostate cancer is required;

With respect to Groups 180-200, the Examiner suggests that election between the patentably distinct species of paramagnetic ions or a radioisotope is required.

Applicants respectfully traverse this rejection.

MPEP §803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A proper search of the prior art relating to a CSG of Groups 1-20 should also reveal art relating to the gene product encoded thereby and uses thereof as set forth in the claims of Groups 21-240. Thus, it does not appear that a serious burden would be placed upon the Examiner if restriction to the specified Groups were not made.

Further, the Examiner has provided no evidence whatsoever in this Restriction Requirements to support the contention that the Groups have acquired separate status in the art nor that the searches for the groups are not co-extensive. No class or subclass numbers have been defined by the Examiner for any of the Groups of this Restriction Requirement.

Accordingly, since this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper, ~~it~~ is respectfully requested that this Restriction Requirement be withdrawn.

Applicants also respectfully disagree with the Examiner's characterization of the cancer specific genes of SEQ ID NO:1-20 as separate inventions rather than species. In accordance with MPEP §806.04(f), for claims to be restricted to different species, the claims must be generally exclusive. The general test as set forth in MPEP §806.04(f) is that one claim recites limitations which under the disclosure are found in a first species but not in a second species, while a second claim recites limitations disclosed only for the second species and not the first. In the instant application, however, there are no claims reciting limitations for only one CSG or gene product encoded thereby and not for another. Accordingly, restriction to one of the CSGs of SEQ ID NO:1-20 is improper as the CSGs are related species under the instant disclosure subjectable to a species election requirement.

In accordance with MPEP § 808.01, an election of species should be made when a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required. In the instant case, however, the claims are not drawn to such a large multiplicity that search of all species would be unduly extensive or burdensome. Only 20 sequences are set forth.

Accordingly, reconsideration of any species election requirement to CSGs of SEQ ID NO:1-20 is also respectfully requested.

Reconsideration of the species election requirement relating to Groups 1-20 of cells and tissues versus bodily fluids is also respectfully requested. Clearly any search of prior art relating to diagnostic methods for prostate cancer using a specified CSG would reveal references teaching diagnostic methods in cells and tissues as well as bodily fluids. Thus, inclusion of both cells and tissues and bodily fluids in one claim can hardly be considered a multiplicity of species requiring an unduly extensive and burdensome search. Accordingly, this species election requirement fails to meet the guidelines for a proper species requirement as set forth in MPEP § 808.01. Withdrawal of this species elections is also therefore respectfully requested.

However, in an earnest effort to be completely responsive, Applicants elect Group 8 relating to determining the presence of prostate cancer by determining the level of a cancer specific gene comprising SEQ ID NO:8, with traverse. Applicants also respectfully request that the Examiner give consideration at least to inclusion of Group 7, SEQ ID NO:7, in the prosecution of this case as well, as searching of only two CSGs clearly

substantially reduces any burden to the Examiner as compared to searching of all 20 CSGs.

Further, Applicants elect as a species for Groups 8 and 7 cells and tissues, with traverse.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,

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